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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/084,855

02/27/2002

Evan C. Unger

UNGR-1632

8641

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EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

11/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/084,855	Applicant(s) UNGER, EVAN C.	
	Examiner Layla Soroush	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 8, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 47, 49-51 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 47, 49-51 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed August 8, 2007 presents remarks and arguments submitted to the office action mailed February 8, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1,47, 49-51, and 55 over Ottoboni et al US Patent 6,193, 951 in view of Grinstaff et al US Patent 5,498,421, Unger et al and Hirota US Patent 4,960,595 is not persuasive. Therefore, the rejection is maintained for reasons of record.

Claims 1,47, 49-51, and 55 are pending.

Claims 1,47, 49-51, and 55 are herein acted on the merits.

The rejection is restated below for applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,47, 49-51, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottoboni et al US Patent 6,193, 951 in view of Grinstaff et al US Patent 5,498,421, Unger et al and Hirota US Patent 4,960,595.

Ottoboni teaches bi-layered shell microspheres containing an outer shell and an inner shell, wherein the outer layer will be a biologically compatible material and the

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inner layer will be a biodegradable polymer tailored to form a core that contains a gas and can further provide drug delivery properties (see col 2, lines 44-67). Ottoboni teaches that the inner layer comprise an organic liquid core that falls within the limitation of the instantly recited oil. (see col 8, lines 1-67). Otobboni fails to specifically employ a lipid component such as a phosphatidic acid in his microspheres. Grinstaff teaches that polymeric shells may be modified with phospholipids to form a stabilized lipid containing microspheres (see claim 26). In fact, Grinstaff teaches similar micropsheres as Ottoboni, except that it comprise a biologic agent, a polymeric shell encapsulating a perfluorocarbon gas. (see col 12, lines 10-40; example 13, 35-37, claims 1, 12-13). Grinstaff only fails to articulate the use of a phosphatidic acid as a lipidic moiety.

Unger teaches delivery systems comprising gas filled liposomes containing a bioactive agent, and an oil (see abstrtact, col 21, line 20-col 22, lines 9-67). The delivery systems of Unger contains one or more phospholipids selected from group phophatidic acid, phosphatidylcholine, phosphatidylethanolamines, perfluorocarbon, and a suitable oils such as glyceryl monostearate, corn oil, olive oil, mineral oil etc... (see col 13, lines 30-45; col 8, lines 10-21; 32, lines 55-65; col 33, lines 5-10). Unger teaches phospatidic acid containing microspheres.

Hirato explicitly says that phosphatidic acid is an auxiliary material that stabilizes dispersions of lipidic microspheres (see col 3, lines 20-44).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to employ at least one lipidic components of Unger in the microspheres of Ottoboni to provide effective drug delivery systems, because as described by Grinstaff,

polymeric shells can be modified to contain phospholipids and as evidenced by Unger and as described by Hirato, phosphatidic acid improves the stability of such microspheres. One of ordinary skill in the art would have been motivated to do such modifications because, as described by Grinstaff, polymeric shells and their phospholipids modified analogs are art recognized functional equivalents. Further, the use of phosphatidic acid is conventionally practiced to improve the stability of such microspheres. Accordingly, the combination of the cited references render the instant claims obvious as it teaches all elements of the instant claims.

Response to Arguments

Applicant's arguments filed on August 8, 2007 have been considered.

Applicant's only argument is that the Declaration under 37 C.F.R. § 1.131 states "this invention was conceived of and reduced to practice prior to the priority date of Ottoboni. Therefore, the present invention was conceived of and reduced to practice prior to the earliest priority date Ottoboni. Accordingly, in accordance with MPEP § § 706.02(b) and 715.01, Ottoboni is considered antedated for the purposes of 35 U.S.C. § 102 (e), and is not available for the purposes of making out a valid prima facie case of obviousness under 35 U.S.C. § 103."

However, Examiner points to the MPEP III.715 [R-3] wherein it is stated "The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits

of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained.”

Applicant has only stated that the claimed invention was conceived in the United States and reduced to practice prior to April 30, 1997, the earliest priority date of U.S. Pat No. 6,193,951 to Ottoboni et al. The Declaration has been acknowledged but is not persuasive in overcoming the rejections of record for the reasons stated above.

The arguments are not persuasive and the rejection is made **FINAL**.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

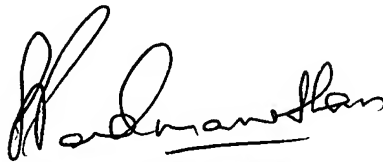
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30

a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER